Remarks

In the Office Action of August 11, 2004, the Examiner rejected the pending claims under 35 U.S.C. § 112 and 35 U.S.C. § 103 in view of U.S. Patent No. 5587180 to Allen, Jr. et al., ("Allen").

The method of the invention is directed to making a fast-dissolve effervescent tablet. The tablets of the invention are made with a two-step process: ingredients are first granulated and then the granulation is compressed into a tablet. In order to obtain rapid dissolution rates, particularly in fast-dissolve tablets with low amounts of water present, such tablets should be highly porous and should fall apart easily. The faster the tablet loses integrity, the faster a large surface area becomes available for dissolving the granulated materials, especially the active ingredients in whatever amount of water is available.

Unfortunately, the very properties that allow a fast-dissolve or effervescent tablet to dissolve quickly also adversely affect the physical properties of the tablet, including hardness and strength. There are ways around this dilemma, and they are set forth in the application. These solutions, however, tend to favor either fast-dissolve/weak structure or slow-dissolve/strong structure solutions. The best compromises between these properties tend to be the most expensive to manufacture. Applicant's invention manages to accommodate these two conflicting properties without expensive processing.

Thus, the process of the invention yields a "fast-dissolve" tablet. As used in this application "fast-dissolve" means from two to twelve seconds (App. Page 5, lines 1-10). Applicant also manufactures effervescent tablets. While effervescent tablets, such as Alka-Seltzer tablets, dissolve readily in water, commercial Alka-Seltzer tablets are not "fast-dissolve" within the meaning of this application.

The Examiner should also note that the invention requires an effervescent tablet. An effervescent couple is used in the tablet to provide intriguing organoleptics for the tablet, but the broadly claimed process does not require voids in the granules or tablets formed by effervescent gas generation during granulation and/or tabletting.

Claim 15 was rejected under Section 112, paragraph 2, because no unit of measure had been supplied for the porosity. The rejection under Section 112 is respectfully traversed. Porosity is defined as the ratio of the volume of voids (pores) in a material to the total (bulk) volume. Thus porosity is a unitless number, not measured in ml/g or any other unit. Another way to state a porosity of 0.4 to 0.7 is that the volume of the tablet comprises from 40% to 70% void spaces. See http://www.geology.wisc.edu/courses/g627/l9_13.html.

The Examiner's attention is directed to column 5, lines 55-67 of Allen. The porosity recited in those discussions is improperly identified. It is given merely as the inverse of the bulk density (1/13 ml/g $\approx$ .077 g/ml; 1/20.4 ml/g $\approx$ 0.049 g/ml). While it is common sense that density and porosity have an inverse *relationship* for a given material, that relationship does not mean that the two properties must be measured in inverse *units*. In the venerable ideal gas law,

PV=nRT, pressure (lb/in.^{2}) and volume (in.^{3}) have an inverse relationship, but they do not have inverse units of measurement.

The claims were also rejected under Section 103 over Allen. Allen, however, is simply inapposite to the claimed invention. While both the claimed invention and Allen are directed to fast-dissolve tablets, Allen takes a very different approach to obtain a fast-dissolve tablet.

The approach of Allen is to make a support matrix using spray-drying techniques. The matrix is then mixed with the active ingredient and tablets are formed in various ways, including compression with a moistening agent. One required feature of Allen is that the matrix must maintain a net electrostatic charge. This charge is maintained by the ingredients selected to form the matrix and an added buffer. It is unclear from the examples whether this material is spray dried once or twice. This matrix is then combined with the active and tabletted.

Step (a) of the claimed invention requires that a predominant part of a combination be granulated. That claimed combination includes the active pharmaceutical ingredient. Allen, on the other hand, only adds the active after forming its particulate support matrix (Col. 6, lines 54-57, Col. 7, l. 29-35). Thus, a predominant part of the claimed active ingredient is found inside the granulation, while all of the Allen active ingredient is found adhered to the surface of Allen's particulate support matrix.

The claimed invention prohibits disintegrants in the mixture, but Allen expressly permits them (Col. 6, line 66 – Col. 7, line 15).

These differences between the claimed invention and Allen are more than the disclosure of the particular pressure and degree of compaction mentioned in the Office Action. Withdrawal of the objections is earnestly solicited.

Respectfully Submitted,

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